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V. 510(K) SUMMARY

ColBar LifeScience Ltd.'s Ossix™-Plus

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

ColBar LifeScience Ltd.
9 Hamenofim St.
P.O. Box 12206,
Herzliya, 46733, Israel

Tel: 972-9-9718666
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Contact Person: Orit Tal-Shmayovits, Director of Regulatory Affairs

Date Prepared: November 21, 2005

Name of Device and Name/Address of Sponsor

Ossix™ Plus

ColBar LifeScience Ltd.
9 Hamenofim St.
P.O. Box 12206,
Herzliya, 46733, Israel

Common or Usual Name

Resorbable dental barrier membrane, animal source

Classification Name

N/A, unclassified device

Predicate Devices

ColBar LifeScience Ltd. - Bio-Bar
Geistlich Pharma's Bio-Gide Resorbable Bilayer Membrane

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Intended Use / Indications for Use

Ossix™-Plus biodegradable collagen membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

- Ridge augmentation for later implant insertions.
- Simultaneous ridge augmentation and implant insertions.
- Ridge augmentation around implants inserted in delayed extraction sites.
- Ridge augmentation around implants inserted in immediate extraction sites.
- Alveolar ridge preservation consequent to tooth (teeth) extraction(s).
- Over the window in lateral window sinus elevation procedures.
- In implants with vertical bone loss due to infection, only in cases where satisfactory debridment and implant surface disinfection can be achieved.
- In intra bony defects around teeth
- For treatment of recession defects, together with coronally positioned flap
- In furcation defects in multi rooted teeth

Technological Characteristics

Ossix-Plus is a resorbable dental membrane made from ribose cross-linked porcine collagen. The membrane provides a barrier that guides bone regeneration, segregates tissue layers, or supports periodontal tissue regeneration. Barrier membranes are placed over bony or periodontal defects to prevent the population by cells from the gingival connective tissue and epithelium. This segregation of tissues by the membrane creates a cavity into which bone forming cells migrate and leads to new bone formation, as well as allowing cementum with inserting periodontal fibers to reform on exposed roots. The regeneration of lost periodontal structures (bone, periodontal ligament, and connective tissue attachment) around teeth is known as guided tissue regeneration ("GTR").

Because Ossix-Plus is a collagen membrane of animal origin, the device resorbs over time (within approximately 8 months based on animal model data). A second surgical procedure to remove the membrane is not required.

Performance Data

To assess the performance of Ossix-Plus, ColBar conducted animal model alveolar defect testing. The conducted tests demonstrated that Ossix-Plus functions as a resorbable barrier membrane in guided bone regeneration. Oral applications, including:

- Ridge augmentation for later implant insertions.
- Simultaneous ridge augmentation and implant insertions.
- Ridge augmentation around implants inserted in delayed extraction sites.
- Ridge augmentation around implants inserted in immediate extraction sites.
- Alveolar ridge preservation consequent to tooth (teeth) extraction(s).
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- In implants with vertical bone loss due to infection, only in cases where satisfactory debridment and implant surface disinfection can be achieved.

Substantial Equivalence

Ossix-Plus is as safe and effective as the Ossix™ and Bio-Gide. The Ossix-Plus has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Ossix-Plus and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Ossix-Plus is as safe and effective as predicate devices. Thus, Ossix-Plus is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 10 2007

Colbar Lifescience Limited
C/O Mr. Jonathan S. Kahan
Hogan & Hartson LLP
555 Thirteenth Street, NW
Washington, DC 2004

Re: K053260
Trade Name: Ossix-Plus
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPL
Dated: February 16, 2006
Received: February 16, 2006

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of February 22, 2006

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Protecting and Promoting Public Health

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IV. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: Ossix™-Plus

Indications for Use:

Ossix™-PLUS biodegradable collagen membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

- Ridge augmentation for later implant insertions.
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- For treatment of recession defects, together with coronally positioned flap
- In furcation defects in multi rooted teeth

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sara Russell

[illegible] General Hospital
[illegible] Devices

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